

§ 890.1

- 890.5380 Powered exercise equipment.
- 890.5410 Powered finger exerciser.
- 890.5500 Infrared lamp.
- 890.5525 Iontophoresis device.
- 890.5575 Powered external limb overload warning device.
- 890.5650 Powered inflatable tube massager.
- 890.5660 Therapeutic massager.
- 890.5700 Cold pack.
- 890.5710 Hot or cold disposable pack.
- 890.5720 Water circulating hot or cold pack.
- 890.5730 Moist heat pack.
- 890.5740 Powered heating pad.
- 890.5765 Pressure-applying device.
- 890.5850 Powered muscle stimulator.
- 890.5860 Ultrasound and muscle stimulator.
- 890.5880 Multi-function physical therapy table.
- 890.5900 Powered traction equipment.
- 890.5925 Traction accessory.
- 890.5940 Chilling unit.
- 890.5950 Powered heating unit.
- 890.5975 Therapeutic vibrator.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 48 FR 53047, Nov. 23, 1983, unless otherwise noted.

Subpart A—General Provisions

§ 890.1 Scope.

(a) This part sets forth the classification of physical medicine devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a physical medicine device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal Regulations are the chapter I of title 21, unless otherwise noted.

[52 FR 17741, May 11, 1987]

21 CFR Ch. I (4–1–99 Edition)

§ 890.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application of premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device

before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commercially distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

[52 FR 17741, May 11, 1987]

§ 890.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

(a) The Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(1) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(2) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharp-

ened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

(b) The exemption from the requirement of premarket notification for a generic type of class II device applies only to those class II devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type, or, in the case of in vitro diagnostic devices, for which a misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality. A class II device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification when:

(1) The device is intended for a use different from the intended use of a legally marketed device in that generic type of device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(2) The modified device operates using a different fundamental scientific technology than a legally marketed device in that generic type of device; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology; or

(3) The device is an in vitro device that is intended:

(i) For use in the diagnosis, monitoring, or screening of neoplastic diseases with the exception of immunohistochemical devices;

(ii) For use in screening or diagnosis of familial and acquired genetic disorders, including inborn errors of metabolism;

(iii) For measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life-threatening diseases such as acquired immune deficiency syndrome